

Applicant's understanding that the Examiner believes the invention to be directed only to absolute protective immunity ,i.e., that anti-recognin antibodies to cancer cells will destroy the cancer cells.

The Examiner's assertion, however, is only partially correct. The present invention encompasses not only absolute protective immunity, but also an immune response to recognin which slows down the tumor growth, thus keeping the cancer at bay and increasing long-term survival of patients having anti-recognin antibodies. In this regard, the actuarial data demonstrate a high correlation between long-term survival and anti-recognin titer. There is no requirement that the present vaccine must protect all patients to the same extent or confer absolute immunity. It is sufficient that the claimed invention confer some immunogenic protection to some patients.

The Examiner states that the actuarial data alone are insufficient to establish biological causality. It is respectfully submitted, however, that Applicant is not merely relying on the actuarial data, but has provided further evidence of the effect of anti-recognin antibody on tumor growth. For example, Applicant has provided data that demonstrate that 1) antibody titer is reduced following tumor removal, indicating that antibody titer is directly responsive to the presence of a tumor; and 2) actuarial data, reduction in antibody titer following tumor removal and in vitro data that demonstrate the cytotoxicity of anti-recognin antibodies. It is respectfully submitted that the totality of the evidence establishes that Recognins elicit protective immunity against cancer. Based on the data as a whole, one of ordinary skill in the art would conclude that anti-recognin antibodies provide some protective immunity to cancer. It is further submitted that the specification teaches how to make and use the claimed invention.

The Examiner stated in the telephone interview referred to above that she would consider evidence in the form of scientific literature that demonstrates that protein vaccines are effective in inducing anti-cancer immunity in animal models. Applicant has enclosed herewith a copy of the proceedings of a symposium which describe a wide range of tumors and animal systems in which immunity to these tumors was induced using a protein vaccine. These abstracts demonstrate that protein vaccines can indeed induce immunity to cancer. Moreover, these abstracts demonstrate that the use of protein vaccines as anti-cancer agents is well accepted in the art. Many of the peptide-based vaccines described in the abstracts are currently being tested in clinical trials. Furthermore, the methods utilized in the protocols described in the abstracts are similar to Applicant's method of inducing immunity.

In particular, abstract S08 reports the anti-tumor effects of vaccination with members of a particular test peptide family. The test peptides are suggested as useful for targeting various types of tumors, including both virus induced and non-virus induced tumors. Abstract S13 describes the use of tumor associated antigens to treat established tumors. These latter authors report that synthetic peptide vaccines elicited specific responses in two mouse model systems and prolonged the survival of thymoma-bearing mice.

It is respectfully submitted that the evidence provided in the above-described abstracts, together with the data presented in the specification demonstrates the correlation between immune response and protective immunity. Furthermore, the in vitro studies disclosed in the specification clearly demonstrate that anti-recognin antibodies are specifically cytotoxic to cancer cells. The totality of the evidence establishes the ability of the anti-recognin antibodies to confer protective immunity.

Moreover, the specification clearly discloses the manner and process of making and using the claimed invention, thus providing an enabling disclosure.

Accordingly, the rejection of claims 1 and 2 under 35 U.S.C. §112 is respectfully traversed.

It is respectfully submitted that the present application is in condition for allowance, an early notification thereof being earnestedly solicited.

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Respectfully submitted,

KENYON & KENYON



Judith L. Toffenetti  
Reg. No. 39,048

KENYON & KENYON  
1025 Connecticut Avenue, N.W.  
Washington, D.C. 20036  
(202) 429-1776 (telephone)  
(202) 429-0796 (facsimile)